

means for compressing the at least one external protuberance, said means for compressing being rotatably coupled to said means for holding, such that relative rotation thereof compresses the at least one protuberance, said means for compressing acting on the stent by exerting a force perpendicular to an axis of the stent.

14. (Original) The apparatus of Claim 13, further comprising,

means for gripping said means for holding the stent to aid in rotating said means for holding relative to said means for compressing.

15. (Original) The apparatus of Claim 14, further comprising, means for gripping said means for compressing the stent.

### **Remarks/Arguments**

### **The Claim Rejections**

The Examiner has rejected Claims 1-4, 6 and 13-15 under 35 U.S.C. 102(b) as being anticipated by Mikus, et al. (2002/0151967). The Examiner has rejected Claims 5 and 7-12 under 35 U.S.C. 103(a) as being unpatentable over Mikus, et al. (2002/0151967).

### **The Response**

Applicant respectfully requests the Examiner to reconsider her rejection of independent Claims 1 and 13. Claim 1 requires, inter alia, a "protrusion compressor having a tab extending therefrom towards said mandrel, said tab **pressing the at least one protrusion of the stent inwardly** toward the lumen of the stent..." Claim 13 calls for "means for compressing... said means for compressing acting on the stent by exerting a force **perpendicular to an axis of the stent.**" (Claim 13). Neither of these features are disclosed in U.S Patent Application No. 2002/0151967 to Mikus et al. ("Mikus") or any of the other references cited. As explained in the specification of the application, tab 56 is an example of a structure meeting the limitations of the

quoted features from independent Claims 1 and 13.

FIG. 13 and 14 of Mikus and the relevant sections of the Mikus specification, e.g., paragraphs 0087-0098 disclose that an outer catheter 115 cooperates with an inner catheter 114 for controlling the position and confirmation of a stent 110 positioned about the inner catheter 114. In Mikus, the stent is retained on the inner catheter 114 by a pull wire 125 extending through a lumen 124 in the wall of the inner catheter 114 and through a hole 127 proximate the distal end of the stent 110. The proximal end of the stent 110 also has a hole 134 accommodating a pull wire 132 for holding the stent in association with the outer catheter 115. FIGS 2 and 3 of U.S. Patent No. 6,413,269 to Bui et al. ("Bui"), a related application, appears to show this arrangement more clearly.

In Mikus, the fixation of the ends of the stent 110 by the respective pull wires 125, 132 permits the stent 110 to be coiled or uncoiled by the relative rotation of the inner lumen 114 and the outer lumen 115. Further, the stent 110 may be released from the delivery catheter 111 by pulling the wires 125, 132 from the holes 127, 134. The structure which the Examiner has referred to as a "hook" that is shown in FIG 14 is also shown in FIG. 13, i.e., in the area identified by reference number 133. Mikus identifies 133 as the "distal extension of the pull wire lumen 131 beyond the annular recess 130". Mikus apparently does not provide a name or a reference number for the "hook" noted by the Examiner, the reference number 133 referring to a lumen through the "hook".

A close review of Mikus reveals that the "hook" is a continuation of the outer catheter 115 (around the recess 130) that provides a support for the pull wire 132 after it passes through the hole 134 in the proximal end of the stent, i.e., in the distal extension 133 of the pull wire lumen 131. As shown in FIG. 13 and described in paragraphs 0090 and 0091, the "hook" has an outer diameter approximating the outer diameter of the stent 110 when the stent 110 is tightly wound on the inner catheter 114. As a result, the "hook" inserts between the proximal end of the stent 110 and the immediately adjacent proximal coil of the stent 110. This is

consistent with its function of receiving the pull wire 132, i.e., within lumen extension 133. Due to a shared diameter, the "hook" in Mikus must be disposed between the coils and therefore can not over-ride them. As a result, the "hook" of Mikus, unlike the tab of Claim 1, does not **press the at least one protrusion of the stent inwardly** toward the lumen of the stent, nor does it compress the stent by exerting a force **perpendicular to an axis of the stent**, like the means for compressing claimed in Claim 13.

As a result, Mikus fails to anticipate the features of Claims 1 and 13. Further, Mikus clearly teaches away from use of the "hook" as a member for pressing the stent due to its substantially different and specialized structure and functional relationship relative to the stent. The "hook" has the same outer diameter as the stent and therefore can not over-ride or press the stent inwardly. In addition, the overall functionality of the Mikus device is incompatible with the present invention as claimed in the independent claims and suffers from the limitations of the prior art. Mikus requires lumens 124, 131 to be formed in the walls of the inner and outer catheters 114, 115 and holes 127, 134 in the ends of the stent 110 to pass the pull wires 125, 132. The pull wires are threaded through the lumens and through the holes in the ends of the stent and then through a further extension of the lumens beyond each of the stent holes. The pull wires constrain the extreme ends of the stent to control coiling and uncoiling of the stent (via relative rotation of the inner and outer catheters) and allow the stent to be released when the pull wires are drawn back, out of the holes in the stent.

In contrast, the present invention provides an apparatus that can be used to focus coiling and uncoiling to one end of the stent, i.e., the enlarged coil(s). This is done by frictionally engaging the stent at the stent fixation zone and then coiling/uncoiling the enlarged proximal coil(s) **only**. Moving the extreme proximal end of a stent relative to the extreme distal end (as in Mikus) differs from moving the proximal end of the stent relative to where the stent first contacts the stent retention zone distally of the enlarged coil(s), because in the latter case, all coiling/uncoiling is focused on the enlarged proximal coil(s) rather than being distributed along

the entire length of the stent. The practical implications of this difference is that for stents with enlarged coils other than proximal enlarged coil(s), the act of winding down the proximal enlarged coil(s) would also require simultaneously winding down all other enlarged coil(s). So, e.g., if winding the proximal coil(s) requires 90 degrees of relative turning (of the external and internal catheters in Mikus and of the mandrel and latch assembly in the present invention) and distal enlarged coil(s) require 90 degrees of relative turning to wind down, then the present invention would only require 90 degrees of turning to wind down the proximal enlarged coil, while the Mikus device would require 180 degrees of relative turning. Further, the winding down of coils other than proximal coils has implications on overall stent length, viz., the more effected coils, the greater the change in length. Accordingly, if the length increase attributable to winding down a proximal coil(s) is "X" and the length increase attributable to winding down a distal coil(s) is "Y", then the overall length increase in the stent wound down by the Mikus device would be "X+Y", but only "X" using the present invention. Limiting the change in coil length attributable to coiling/uncoiling a stent promotes easier and more accurate placement of the stent, viz., because the target area is small and inaccessible and the less the stent changes in length when changing state from coiled to uncoiled, the greater the likelihood that the placed stent will be properly aligned with the target area.

### **The Dependent Claims**

Because each of the independent claims distinguish over the references cited, all claims depending therefrom should also be patentable. The dependent claims also recite additional features which further distinguish over the references. For example, Claim 4, as amended herein, specifies that the stent fixation zone has an outer diameter that is greater than the interior diameter of at least a portion of the lumen of the stent prior to installation of the stent on the mandrel. This gives rise to a frictional engagement of the stent on the mandrel when it is placed thereon. Mikus does not exhibit this type of relationship, in that the internal diameter of

the stent 110 in Mikus is defined by the external diameter of the inner catheter 114. This is because the stent is wound about the inner catheter 114 while in the Martensite state. By definition, the internal diameter of the stent 110 can therefore never be less than the external diameter of the inner catheter 114. As a result, there is no frictional engagement of the stent by the inner catheter 114 due to the relationship claimed in Claim 4.

Owing to the foregoing relationship claimed in Claim 4, a taper permits the gradual introduction of the stent over the stent retention zone as claimed in Claim 5. In Mikus, there is no need for a taper to introduce the stent over the inner catheter 114 about which it is wound. Applicant does not understand the Examiner's proposed reasoning pertaining to the prevention of damage to workers or the easing of construction attributable to a taper on the mandrel and therefore respectfully requests the Examiner to explain these proposed ideas with an example from the prior art if this basis for rejection is maintained.

Claim 7 differs from Mikus in that the collar 118 of Mikus is not coaxially received on the removable collet 137 (which the Examiner has denominated the "hub"). Further, the collar 118 in Mikus is not restrained from rotating by a pin extending through the collar 118 and into an elongated slot in any member, in particular, the removable collet 137. Since there is no comparable pin and slot in Mikus, there is no constraint in the motion of the collar to a telescopic movement on the removable collet 137. In Mikus, the pin 210 prevents movement of the sheath 116 and is not received in an elongated slot in the hub in the removable collet 137 to constrain the collar 118 to telescopic movement along a length of travel limited by a slot.

As to Claim 9, Mikus does not disclose a grip portion with a hollow post. The Examiner has proposed that the outer catheter 115 has a hollow post, in that the interior catheter 114 passes through the outer catheter 115. The Examiner is apparently proposing that the inner catheter 114 of Mikus is the equivalent of the mandrel of the present invention and is also, simultaneously, the equivalent of the hollow post claimed in Claim 9. Applicant respectfully suggests that the inner catheter 114 cannot simultaneously be both elements. Further, Mikus

never teaches that the "hook" should extend over the relief slot 123 because there is no purpose for doing so. The entire disclosure of Mikus is inconsistent with that interpretation and teaches away from it. In Mikus, the relief slot 123 receives the distal end of the stent which is held by a pull wire 125. The hook cannot overextend the release slot 130 because relief slot 130 indeed defines the "hook", which is in-artfully depicted in Fig. 14. Relief 130 is provided in the outer catheter 115 and receives the proximal end of the stent 110, which is held there by a pull wire 132. In short, Mikus has no relief slot under the stent coil aligned with an overriding tab to conjointly hold the stent.

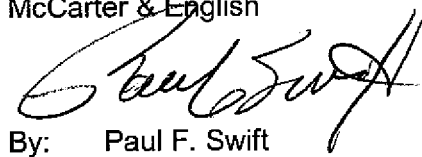
The patentable distinctions pointed out in Claim 10 are further emphasized in Claim 11.

In light of the foregoing amendments and remarks. Applicant believes that the claims as now presented are patentable. Applicants' attorney thanks the Examiner for the effort expended in examining the application and respectfully requests reconsideration of the amended claims.

No fees are thought to be required, however, if any fees due as a result of this Response, the Examiner is authorized to charge them to Deposit Account No. 503571.

Respectfully Submitted,

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